

K964565
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510(k) Summary of Safety and Effectiveness Information

The Paramax® Ammonia and Ammonia Blank Reagent is substantially equivalent to its predecessor, which was cleared to market on K770363. The proposed and the predicate device are intended for use as quantitative determination of Ammonia and Ammonia Blank in plasma.

The Paramax® Ammonia and Ammonia Blank Reagent and DuPont aca Ammonia and Ammonia Blank Reagent are GLDH enzymatic method.

The technological characteristics of the predicate device are similar to those previously described for the proposed device.

The correlation between the Paramax® Ammonia and Ammonia Blank Reagent and DuPont aca Ammonia and Ammonia Blank Reagent was demonstrated by testing 197 samples on a Paramax® and DuPont aca Systems. The correlation coefficient was 0.986, and the regression equation was $\text{Paramax® value} = (0.980 \times \text{aca value}) - 8.8$. The data indicates that the results obtained by both reagents are substantially equivalent.